

REMARKS

This Amendment is responsive to the Examiner's Final Office Action dated December 28, 2009. By way of summary, Claims 5, 7-9, 11, 27, 28, 37, 53-74 and 76-86 were pending in this application. Applicants have hereby amended Claims 27, 28, 66, 74, 82 and 86, and canceled Claims 5, 7-9, 11, 53-65 and 77-81. Thus, Claims 27, 28, 37, 66-74, 76 and 82-86 are presently pending in this application. Reconsideration of the application in view of the foregoing amendments and following remarks is respectfully requested.

As a preliminary matter, Applicants would like to thank Examiner Katherine M. Dowe for the courteous Interview (the "Interview") extended to Applicants' Attorney William H. Shreve on February 25, 2010.

Claims 27, 28, 37, 66-74, 76 and 82-86 are Patentable Over the Applied Combination

The Examiner rejected Claims 5, 7-9, 11, 27, 28, 37, 53-74 and 76-86 under 35 U.S.C. § 103(a) as being obvious in view of the combination of U.S. Patent Nos. 6,544,249 B1, 6,464,724 B1 and 6,050,99 to Yu et al. ("Yu"), Lynch et al. ("Lynch") and Paraschac et al. ("Paraschac") respectively.

Applicants respectfully traverse these rejections and the Examiner's characterization of the cited references on the bases set forth below.

In this case, to advance prosecution, independent Claims 27, 28, 66, 74 and 82 have been amended and apparatus Claims 5, 7-9, 11, 53-65 and 77-81 have been canceled, as shown above. (Dependent Claim 86 has been amended in view of the amendment to Claim 82.) Thus, only method claims are presently pending in this application.

Support for the above amendments can be found in the Application as originally filed, and no new matter has been introduced. See, for example, paragraph numbers [0049], [0300], [0313], [0315] of the Specification and FIGS. 51A, 53, and 36.

Applicants reserve the right to pursue the subject matter of any of the prior versions of the claims, including the claims canceled herein, in one or more related applications (including any applications that have at least one listed inventor or assignee in common with the present application) and/or at a later date.

The Examiner asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Yu with Lynch such that

multiple implants were delivered, without removing the instrument from the eye between deliveries, to create additional flow channels and improve the flow of aqueous humor from an anterior chamber to a fluid outflow path of the eye and thereby reduce intraocular pressure in more severe cases. The Examiner further asserted that it would have been obvious to modify the combination of Yu and Lynch with Paraschac such that the multiple implants were arranged end to end within a tube to be serially dispensed by an actuator in a controlled manner.

Applicants' respectfully disagree with the Examiner's assertions. There is no evidence that Yu contemplated implanting multiple implants in the eye as set forth in Applicants' claims. To the contrary, Yu teaches away from such multiple implantations. Yu clearly teaches that a single implant (soluble microfistula tube) will achieve the stated objective of draining excess aqueous humor from an eye to lower intraocular pressure (IOP). Yu additionally notes the importance of preventing over-drainage of aqueous humor. Yu states at column 1, lines approx. 40-45 (emphasis added):

An object of the present invention is to provide a biological microfistula tube subject to reduced rejection effects, that will lead to the formation of a microfistula for permanent or long-term aqueous fluid bypass, **with minimal overdrainage**, and tending to impede wound healing processes and hence the closure of the drainage pathway.

Yu further states at column 2, lines 16-20 (emphasis added):

Consequently a microfistula tube size smaller than has been feasible with prior art devices or techniques may be employed, thereby **reducing the risk of overdraining the aqueous fluid**.

In view of the unambiguous teaching that a single implant will sufficiently lower IOP to treat glaucoma without creating a hypotonic condition and in view of the stated concern of preventing over-drainage, one skilled in the art would not have read Yu to teach or suggest the use of multiple implants, as the Examiner suggests (for example, at page 6, item 6 of the Office Action). In fact, one skilled in the art would read Yu to teach away from the use of multiple implants and would be led away from utilizing multiple drainage implants.

Lynch is directed to stent devices that are wholly contained within Schlemm's canal and do not extend into the anterior chamber of the eye. The primary purpose of these devices is "to expand the canal's dimensions and maintain its patency." See, for example, column 4, line

approx. 28. Given Schlemm's canal's circumferential anatomy, Lynch provides a multi-site solution to address a particular problem.

Similarly, Paraschac is directed to multiple corneal implants to adjust corneal curvature and to correct vision abnormalities. See, column 1, lines 62-65. As one can imagine, without the use of multiple implants to maintain proper corneal symmetry, the resulting vision would be distorted. In Paraschac, the nature of the vision correction also requires multi-site solution to achieve its intended result.

It requires an untenable leap in logic to combine Yu, Lynch and Paraschac since the mere use of multiple implants in an eye, as taught by Lynch and Paraschac, would not lead one of ordinary skill in the art to place multiple drainage implants in the eye. The fact that Paraschac discloses the use of multiple implants in the cornea for optical symmetry does not provide any reason to use multiple implants to shunt aqueous humor from the anterior chamber. Similarly, Lynch's teaching of using a series of stents along a length of Schlemm's canal to increase the canal's patency does not provide any reason to use multiple drainage implants to provide a plurality of drainage courses from the anterior chamber. Accordingly, the site-specific, application-specific teachings of Lynch and Paraschac do not apply to the aqueous drainage issues addressed by Yu and Applicants. Moreover, Yu clearly teaches away from the use of multiple implants for aqueous drainage from the anterior chamber of the eye. As such, the stated reasons to combine the references were predicated upon faulty logic.

The combination of Yu, Lynch and Paraschac thus is improper as the teaching of these references would clearly lead one skilled in the art away from making the suggested combination and there exists no sustainable reason in the record to combine these references together. Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* showing of obviousness.

The Examiner asserted, with respect to some of the rejected claims, at page 4, lines 6-19 of the Office Action:

... it is old and well known in the art to use imaging techniques throughout surgical procedures to identify target locations and monitor the placement of devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu

et al., Lynch et al. and Paraschac et al. such that the locations of the implants were determined by imaging collector channel locations.

... it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that first and second implants were spaced at least 20 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272,205 USPQ 215). Furthermore, it would have been obvious to try placing the first and second implants at least 20 degrees apart since it is obvious to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success.

Applicants again respectfully disagree with these assertions by the Examiner. As noted above, the benefits of targeted implantation in an eye were neither known nor appreciated by others of skill in the art prior to Applicants' discovery thereof. For example, FIG. 41 and paragraph numbers [0037], [0051] and [0231] of the Specification as filed disclose targeted drainage implant delivery based on imaging collector channel locations, and paragraph number [0251] of the Specification as filed states (emphasis added):

The programmed (also know as "Targeted") stent placement refers to the **intentional placement of a stent or stents at a particular location or locations in Schlemm's canal** for the purpose of providing a benefit in the form of more optimal outflow.

Applicants discovered the benefits achieved, in some cases, by determining implant location sites by imaging collector channel locations and, in some cases, by providing a predetermined angular spacing, in one embodiment of at least 20 degrees, between implantation sites that were not recognized by others of skill in the art. Thus, among other reasons as discussed above, Applicants submit that the claims directed to this subject matter are not rendered obvious by the prior art, including the applied combination.

The Examiner further asserted, with respect to some of the rejected claims, at page 5, lines 5-17 of the Office Action:

... Yu et al. do not disclose the implant is placed in the uveal scleral outflow path of the eye. Lynch et al. teach aqueous humor is normally drained out of the eye through two different routes: "In the "uveoscleral" route, the fluid percolates between muscle fibers of the ciliary body. This route accounts for

approximately ten percent of the aqueous outflow in humans. The primary pathway for aqueous outflow in humans is through the "canalicular" route that involves the trabecular meshwork and Schlemm's canal" (col 1, 11 35-48). Therefore, it would have been obvious to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the first and second locations were in the uveal scleral outflow path of the eye as the uveal scleral outflow path of the eye is a well known normal anatomical drainage location and is a known alternative to the trabecular meshwork outflow path of the eye if the implant is unable to be implanted through the trabecular meshwork in a particular patient.

Applicants again respectfully disagree with this assertion by the Examiner for at least the reasons presented above. Thus, Applicants submit that the claims directed to this subject matter are not rendered obvious by the prior art, including the applied combination.

Implant Outlet Orifice Positioning in Instrument

Additionally, as shown and noted above, the independent claims have been amended to recite, *inter alia*, that "when said implants are positioned in said instrument at least one of said implants has an outlet orifice positioned in a direction transverse to an axis of said instrument." This amendment further distinguishes Applicants' claims from the prior art since Yu discloses an implant 10 with a single outlet orifice at end 12 (see FIG. 1) which is coaxial with the surgical instrument's 30 axis when the implant 10 is positioned in the instrument 30 (see, e.g., FIG. 2).

Claims

Turning now to the specific claims, independent Claim 27 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

conveying aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye using said first implant and said second implant;

wherein said locations are determined by imaging collector channel locations; and

wherein when said implants are positioned in said instrument at least one of said implants has an outlet orifice positioned in a direction transverse to an axis of said instrument.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these limitations. Thus, Claim 27 is patentable over the applied combination.

Claim 37 depends from Claim 27 and is patentable for at least the same reasons that Claim 27 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 27 and 37 are in condition for allowance.

Independent Claim 28 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

conveying aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye using said first implant and said second implant;
wherein said locations are angularly spaced along Schlemm's canal by at least 20 degrees; and
wherein when said implants are positioned in said instrument at least one of said implants has an outlet orifice positioned in a direction transverse to an axis of said instrument.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these limitations. Thus, Claim 28 is patentable over the applied combination. Moreover, this claim defines over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claim 28 is in condition for allowance.

Independent Claim 66 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

providing a plurality of biocompatible implants that, when implanted, convey aqueous humor from an anterior chamber of the eye to a physiologic outflow pathway of the eye;
utilizing said instrument to deliver a first biocompatible implant through a wall of a physiologic outflow pathway at a first location within the eye; and
utilizing said instrument to deliver a second biocompatible implant through a wall of said physiologic outflow

pathway at a second location within the eye, without removing said instrument from the eye between said deliveries of said implants;

wherein when said implants are positioned in said instrument at least one of said implants has an outlet orifice positioned in a direction transverse to an axis of said instrument.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these steps. Thus, Claim 66 is patentable over the applied combination.

Claims 67-73 depend from Claim 66 and are patentable for at least the same reasons that Claim 66 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 66-73 are in condition for allowance.

Independent Claim 74 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

utilizing the instrument to **deliver a first implant** through eye tissue so as to place a portion of the first implant in a uveal scleral outflow path of the eye;

utilizing the instrument to **deliver a second implant** through eye tissue so as to place a portion of the second implant in the uveal scleral outflow path, without removing the instrument from the eye between the deliveries of the implants; and

conveying aqueous humor from an anterior chamber of the eye to the uveal scleral outflow path using the implants;

wherein when said implants are positioned in said instrument at least one of said implants has an outlet orifice positioned in a direction transverse to an axis of said instrument.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these steps. Thus, Claim 74 is patentable over the applied combination.

Claim 76 depends from Claim 74 and is patentable for at least the same reasons that Claim 74 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited

therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 74 and 76 are in condition for allowance.

Independent Claim 82 is directed to a method of delivering a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

utilizing said instrument to deliver a **first implant into eye tissue at a first location within the eye;**

utilizing said instrument to deliver a **second implant into eye tissue at a second location within the eye; and**

conveying aqueous humor from an anterior chamber of the eye to a physiologic outflow pathway of the eye using the implants;

wherein when said implants are positioned in said instrument at least one of said implants has an outlet orifice positioned in a direction transverse to an axis of said instrument.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these steps. Accordingly, Applicants submit that Claim 82 is patentable over the applied combination.

Claims 83-86 depend from Claim 82 and are patentable for at least the same reasons that Claim 82 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 82-86 are in condition for allowance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other

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broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed	Attorney Docket No.
10/889,254	OCULAR IMPLANT WITH ANCHOR AND THERAPEUTIC AGENT	July 12, 2004	GLAUKO.1C2C3
12/366,242	IMPLANT AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS	February 5, 2009	GLAUKO.1C2C3DV1
12/772,889	OCULAR IMPLANT WITH THERAPEUTIC AGENTS AND METHODS THEREOF	May 3, 2010	GLAUKO.1C3CP1C1
11/124,440	METHOD OF DELIVERING AN IMPLANT FOR TREATING AN OCULAR DISORDER	May 6, 2005	GLAUKO.1C4C2
12/366,565	OCULAR IMPLANT WITH ANCHOR AND METHODS THEREOF	February 5, 2009	GLAUKO.1C4C11
12/437,482	METHOD OF DELIVERING AN IMPLANT FOR TREATING AN OCULAR DISORDER	May 7, 2009	GLAUKO.1C4C12
10/950,175	IMPLANT WITH INTRAOCULAR PRESSURE SENSOR FOR GLAUCOMA TREATMENT	September 24, 2004	GLAUKO.5C1CP1
11/598,542	IMPLANT AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS	November 13, 2006	GLAUKO.011C1
12/111,033	SYSTEM FOR TREATING OCULAR DISORDERS AND METHODS THEREOF	April 28, 2008	GLAUKO.011C1C1

Serial Number	Title	Filed	Attorney Docket No.
12/366,508	SELF-TREPHINING IMPLANT AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS	February 5, 2009	GLAUKO.011C1DV1
12/366,585	OCULAR IMPLANT DELIVERY SYSTEM AND METHODS THEREOF	February 5, 2009	GLAUKO.011C1DV2
11/836,106	DEVICES AND METHODS FOR TREATMENT OF OCULAR DISORDERS	August 8, 2007	GLAUKO.11CP1C1
11/836,112	DEVICES AND METHODS FOR TREATMENT OF OCULAR DISORDERS	August 8, 2007	GLAUKO.11CP1C2
11/084,314	OCULAR DISORDER TREATMENT IMPLANTS WITH MULTIPLE OPENINGS	March 18, 2005	GLAUKO.11CP2CP1
12/246,448	DRUG ELUTING OCULAR IMPLANT WITH ANCHOR AND METHODS THEREOF	October 6, 2008	GLAUKO.11CP3DV1
11/860,785	OCULAR IMPLANT WITH DOUBLE ANCHOR MECHANISM	September 25, 2007	GLAUKO.013C1DV1
11/455,598	IMPLANT DELIVERY SYSTEM AND METHODS THEREOF FOR TREATING OCULAR DISORDERS	June 19, 2006	GLAUKO.017C1
11/455,391	IMPLANT DELIVERY SYSTEM AND METHODS THEREOF FOR TREATING OCULAR DISORDERS	June 19, 2006	GLAUKO.017C2
11/332,746	FLUID INFUSION METHODS FOR OCULAR DISORDER TREATMENT	January 12, 2006	GLAUKO.020C1
11/653,815	COMBINED TREATMENT FOR CATARACT AND GLAUCOMA TREATMENT	January 16, 2007	GLAUKO.022C1
10/338,743	OCULAR IMPLANT WITH ANCHORING MECHANISM AND MULTIPLE OUTLETS	December 18, 2008	GLAUKO.035DV1
11/938,238	UVEOSCLERAL SHUNT AND METHODS FOR IMPLANTING SAME	November 9, 2007	GLAUKO.099A

Additionally, Applicants wish to point out that claims very similar to the claims as pending in this application prior to the present amendment are pending and presently stand rejected in Applicant's application no. 11/836,106 noted above. Copies of this and other applications, and pending claims, including any office actions and allowances, and any publications are available through PAIR. However, if the Examiner so requests, Applicants will be happy to provide the Examiner with copies of any publications, applications, pending claims, office actions, allowances, or any other documents, at any time.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments may have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Applicants also reserve the right to later contest whether a proper reason exists to combine the applied references as well as to later present facts and arguments supporting the non-obviousness of the claimed subject matter.

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Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly. Also, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 25 June 2010

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